
CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 597

Date: JUNE 24, 2005

CHANGE REQUEST 3836

SUBJECT: Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing

I. SUMMARY OF CHANGES: The Internet Only Manual (IOM) Publication 100-04, chapter 32, section 100, has been added to reflect coverage and billing for ultrasonic osteogenic stimulators. Effective April 27, 2005, CMS determines that the evidence is adequate to conclude that non-invasive ultrasound stimulation for the treatment of nonunion bone fractures prior to surgical intervention is reasonable and necessary.

NOTE: Ultrasound stimulation for nonunion fracture healing is currently a covered service. However claims processing guidance for this service was never added to the claims processing manual. Previous coverage and new coverage requirements are being added per this instruction.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: April 27, 2005

IMPLEMENTATION DATE: August 1, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	32/110/Table of Contents
N	32/110/Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing
N	32/110.1/Coverage Requirements
N	32/110.2/Intermediary Billing Requirements
N	32/110.3/Bill Types
N	32/110.4/Carrier and Intermediary Billing Instructions
N	32/110.5/DMERC Billing Instructions

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Attachment – Business Requirement

Pub. 100-04	Transmittal: 597	Date: June 24, 2005	Change Request 3836
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SUBJECT: Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing

I. GENERAL INFORMATION

A. Background: The CMS announced a Reconsideration of the National Coverage Determination (NCD) covering the use of Ultrasonic Osteogenic Stimulators, effective April 27, 2005.

An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. The device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not to be used concurrently with other non-invasive osteogenic devices.

B. Policy: Effective for services performed on or after April 27, 2005, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion bone fractures prior to surgery. In demonstrating non-union fractures, CMS expects:

A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

Nonunion fractures of the skull, vertebrae, and tumor-related fractures are excluded from coverage. Additionally, ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains non-covered.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F	R	C	D	Shared System Maintainers			Other	
		I	H	a	M	F	M	V	C	
			H	r	E	I	C	S	W	
			I	i	R	S	S	S	F	
			e	r	C					

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3836.1	<p>Effective for dates of service on or after April 27, 2005, carriers & RHHIs shall allow payment for ultrasonic osteogenic stimulators with the following CPT Code:</p> <ul style="list-style-type: none"> • 20979 Low intensity ultrasound stimulation to aid bone healing, noninvasive (non-operative) 		X	X		X				
3836.2	<p>Effective for dates of service on or after April 27, 2005, DMERCs shall allow payment for ultrasonic osteogenic stimulators with the following HCPCS Codes:</p> <ul style="list-style-type: none"> • HCPCS codes: E0760 for low intensity ultrasound, or E1399 for other ultrasound stimulation 				X					
3836.3	As in other cases, if data analysis indicates potentially aberrant billing, contractors shall utilize these standards when performing medical review of claims.		X	X	X					
3836.4	RHHIs shall pay for ultrasonic osteogenic stimulators only when services are submitted on type of bills (TOBs) 32X, 33X, or 34X.		X			X				
3836.5	RHHIs shall instruct HHAs that ultrasonic osteogenic stimulators must be in the patient’s home health plan of care if billed on TOBs 32X or 33X.		X							
3836.6	FIs must instruct hospitals that there are no covered services for ultrasonic osteogenic stimulation for which hospitals can be paid by the FI.	X	X							
3836.7	The shared system shall only make payment for ultrasonic osteogenic stimulators for claims submitted by HHAs on TOBs 32X, 33X, or 34X.				X					

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3836.8	RHHIs shall pay HHAs on TOBs 32X, 33X and 34X for ultrasonic osteogenic stimulators on the DMEPOS fee schedule.		X							
3836.9	Contractors shall adjust claims with dates of service on and after April 27, 2005, through July 30, 2005, if brought to their attention.	X	X	X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3836.10	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "Medlearn Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X					

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: April 27, 2005 Implementation Date: August 1, 2005</p> <p>Pre-Implementation Contact(s): Niccole Corbin (ncorbin@cms.hhs.gov), 410-786-2273 (coverage); Yvette Cousar (ycousar@cms.hhs.gov), 410-786-2160 (carrier claims); Taneka Rivera (TRivera@cms.hhs.gov), 410-786-9502 (FI claims); Wendy Knarr (WKnarr@cms.hhs.gov), 1-800-735-2258 (DMERC claims).</p>	<p>Medicare contractors shall implement these instructions within their current operating budgets.</p>
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Post-Implementation Contact(s): Appropriate RO	
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Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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110 – Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing

(Rev.597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. This device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not to be used concurrently with other non-invasive osteogenic devices.

110.1 – Coverage Requirements

(Rev.597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Effective for dates of service on and after April 27, 2005, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion bone fractures prior to surgical intervention. In demonstrating nonunion fractures, CMS expects:

- A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.*

For further coverage information, please refer to the National Coverage Determinations Manual, Pub. 100-03, chapter 1, section 150.2.

110.2 – Intermediary Billing Requirements

(Rev.597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

RHHIs will pay for ultrasonic osteogenic stimulators only when services are submitted on type of bills (TOBs) listed under Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 100.3.

Fiscal intermediaries (FIs) must educate hospitals that there are no covered services for Ultrasonic Osteogenic Stimulation for which hospitals can be paid by the FI.

NOTE: Hospitals can not bill for Ultrasonic Osteogenic Stimulators.

110.3 – Bill Types

(Rev.597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Only the following TOBs can bill for Ultrasonic Osteogenic Stimulators: 32X, 33X, 34X, which is payable under the DMEPOS Fee Schedule.

NOTE: *Ultrasonic Osteogenic Stimulators must be in the patient's home health plan of care if billed on TOBs 32X or 33X.*

***110.4 – Carrier and Intermediary Billing Instructions
(Rev.597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)***

Effective for dates of service on or after April 27, 2005, contractors shall allow payment for ultrasonic osteogenic stimulators with the following current procedural terminology (CPT) code:

- *20979 - Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)*

***110.5 – DMERC Billing Instructions
(Rev.597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)***

Effective for dates of service on or after April 27, 2005, DMERCs shall allow payment for ultrasonic osteogenic stimulators with the following HCPCS codes:

- *E0760 for low intensity ultrasound, or;*
- *E1399 for other ultrasound stimulation*